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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,490	08/25/2000	Robert R. Whittle	5573-124	5616

7590 05/20/2004

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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/648,490	WHITTLE ET AL.	
	Examiner	Art Unit	
	Brian S Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Summary of Action

I. The rejection of claims 3-6 under 35 USC 112, second paragraph, will be maintained for the reason of the record.

II. The rejection of claims 3, 5 and 6 under the judicially created doctrine of double patenting will be maintained for the reason of the record.

III. Claims 3-6 are rejected under the judicially created doctrine of double patenting over claims 1-4 of US 6,667,324, claims 1-30 of US 6,653329, 1-5 of US 6,268,385 and clams 9-16 of US 6,262,086.

IV. Claim 3-4 and 6 are rejected under 35 U.S.C. 102(b) as anticipated by Junggren et al. (US 4255431).

Status of Application

1. By an amendment filed November 19, 2003, Claims 1-2 have been cancelled and Claims 3 and 6 have been amended. Claims 3-6 are currently pending for prosecution on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is analogous to the original rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 3-4 and 6 are rejected under 35 U.S.C. 102(b) as anticipated by Junggren et al. (US 4255431).

Junggren teaches a composition comprising 2-[2-(3,5-dimethyl-4-methoxy)-pyridylmethylsulfinyl]-(5-methoxy)-benzimidazole (omeprazole), wherein said omeprazole is formulated in various dosage forms (claim 20; column 5, line 59 thru column 7, line 18).

Although Junggren is silent about "fixed with ratio of 5-methoxy and 6-mehtoxy isomer" or "fixed with a ratio of from about 11 percent or less 5-methoxy and from about 89% or more 6-methoxy" or "a predetermined ratio of 5-methoxy and 6-methoxy", such ratio must be inherently present in the composition, i.e., it was always there. Since 5-methoxy and 6-methoxy isomers is presented in 7:93 $\pm$2% in omeprazole or commercially available Prilosec (page 5, lines 6-7 and page 18, lines 10-14 of the specification), the referenced composition containing omeprazole "metes and bounds" the claimed invention. Therefore, the reference anticipates the claimed invention.

It is noted to applicant that the fact that applicant may have discovered a new property of omeprazole (where omeprazole further comprises 6-methoxy in addition to known 5-methoxy

fails to confer patentability to an old composition since such property or characteristic must be inherently present in the old composition. Therefore, the reference anticipates the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 3-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-29 and 32-34 of U.S. Patent No. 6,369,087.

This rejection is analogous to the original rejection.

5. In looking in continuity data, it is noted that applicant has numerous issued patent and pending application encompassing the same or similar subject matter of the instant application. Applicant is aware of the patent and application is requested. Applicant review all subject matter considered same or similar, and submit the proper Terminal Disclaimer(s). For example, claims 1-5 of US 6,268,385, clams 9-16 of US 6,262,086, claims 1-30 of US 6,653329 and claims 1-4 of US 6,667,324. The examiner's time to write each and every rejection is extremely burdensome.

Response to Arguments

6. Applicant's arguments filed November 19, 2003 have been fully considered but they are not persuasive.

In response to the examiner's rejection of the claims under 35 USC 112, second paragraph, applicant alleges that the term "fixed ratio" is discussed in throughout the specification, and reading the claims in light of the specification, those skilled in the art would readily understand what is claimed in the invention. Furthermore, applicant alleges that the recitation of new language "said ratio is determined by Fourier Transform Raman Spectroscopy" renders the claims definite.

The examiner disagrees strongly. Although the term "fixed ratio" is mentioned throughout the specification, the term is not clearly defined for those skill in the artisan to understand what is "metes and bounds" of the instant composition claims. Unlike applicants' argument, the recitation of "said ratio is determined by Fourier Transform Raman Spectroscopy" does not bring any clarity to the claimed invention.

Without a clear definition of the term "fixed ratio" or "fixed with a ratio", such term should give "broadest reasonable interpretation" as possible. The term "fixed" is generally understood as "Not subject to change or variation; constant" (see The American Heritage Dictionary, 2nd Edition, 1976). In light of the readily recognized meaning of the term "fixed", the instantly claimed "fixed with a ratio of 5-methoxy and 6-methoxy isomers" should be in "constant, unchanging, set, not variable" ratio. However, the instantly claimed ratio is in variable range depending upon whatever the ratio determined by Fourier Transform Raman Spectroscopy or the predetermined ratio. Especially, interpreting such term in light of claims 4 and 5 limitation

"from about 11 percent or less 5-methoxy and from about 89 percent or more 6-methoxy" or "from about 17 percent or more 5-methoxy and from about 83 percent or less 6-methoxy" leaves the reader in doubt as to the meaning of the invention to which they refer, thereby rendering the definition of the subject-matter of said claims unclear.

In response to the examiner's rejection of the claims under the judicially created doctrine of double patent, applicant alleges that the cited patent (US 6369087) does not recite that the pharmaceutical formulation is fixed and determined by Fourier Transform Raman Spectroscopy. Furthermore, applicant alleges that the present invention (particularly claim 3) does not recite diasteriomers, metal cations, or one to one ratios.

This argument is not persuasive at all. Although applicant requires "said ratio is determined by Fourier Transform Raman Spectroscopy" in the instant composition, such feature is non-limiting to the claimed interpretation since the instant invention is directed to composition claims. Since the process of determining the ratio by Fourier Transform Raman Spectroscopy does not affect or change the basic characteristic of the claimed composition. The examiner determines that said process of "determined by Fourier Transform Raman Spectroscopy" does not have any patentable weight to the claims.

Although the US'087 does not specifically mention "fixed ratio" 5-methoxy/6-methoxy, the referenced range of "from 1 percent w/w to about 99 percent (w/w)" of 5- and 6-methoxy isomers where the sum of total percentage of such compounds equals about 100 percent (w/w) or the referenced ratio of 1 to 1 of one molecule of 5-and 6-methoxy (in other word 50%:50%)

overlaps with the instantly claimed ratio. Therefore, the reference makes obvious the claimed invention.

With respect to applicant's argument about "the present invention (particularly claim 3) does not recite diasteriomers, metal cations, or one to one ratios", since the instant claim allows for the inclusion of any other unspecified ingredients in said composition by reciting open transitional phrases such as "comprising", the cited patent makes obvious the claimed invention.

Conclusion

7. No Claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (571) 273-0584. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

VICKIE KIM
PRIMARY EXAMINER

Brian Kwon
Patent Examiner
AU 1614